



Controlled Substances and Dangerous Drugs Compliance: Building Blocks for Success



EMORY
UNIVERSITY

Office of Research Integrity and Compliance
Research Compliance and Regulatory Affairs

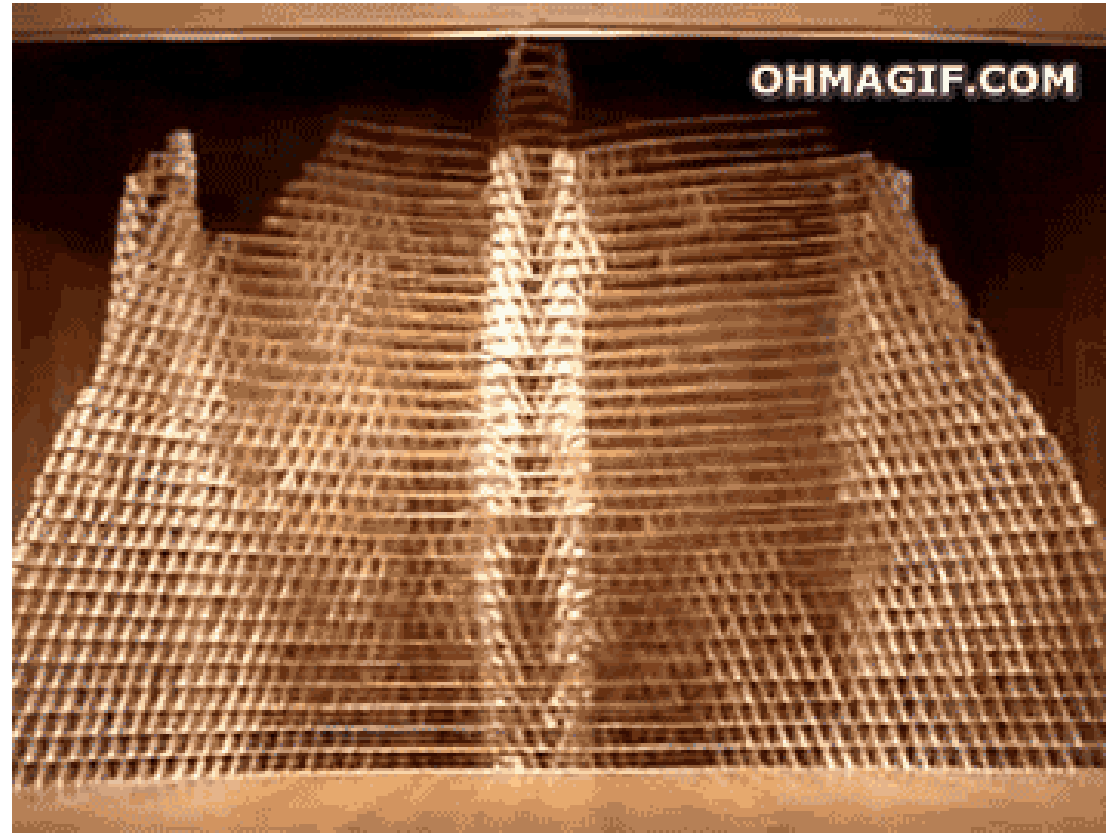
ORIC TEAM:

DANISHA BLOSSAT

MARIA DAVILA

MARGARET HUBER

Expecting compliance without a proper foundation is like...



Building a house with a deck of cards!

In this
presentation

Why compliance matters

The law

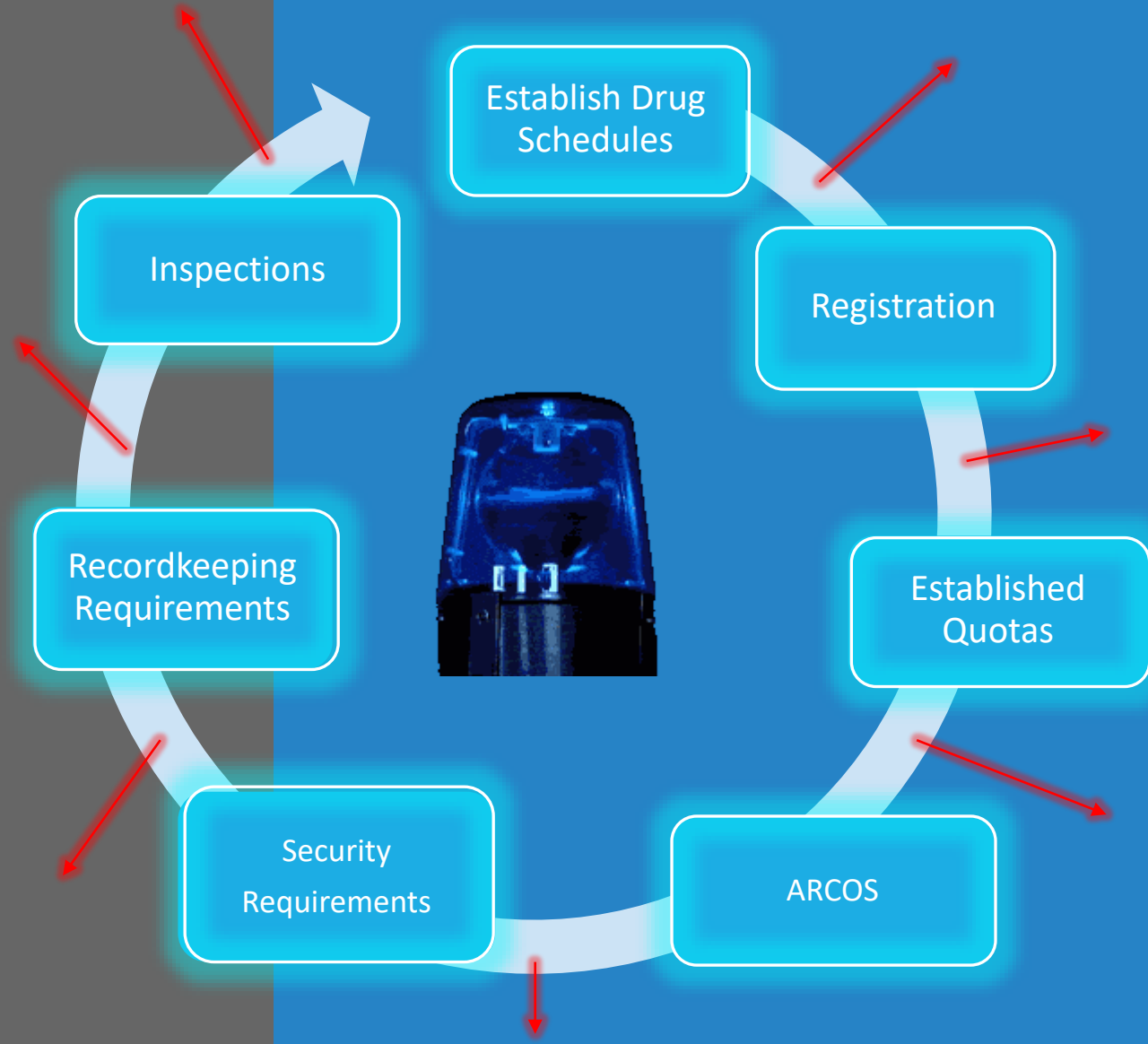
Responsibilities of the
Registrants

Ongoing Training



Office of Research Integrity and Compliance
Research Compliance and Regulatory Affairs

Why does compliance matter?



The Federal and State Regulations are designed to operate within a closed system of distribution for the protection of public health safety to prevent the **diversion** of controlled substances into the illicit market.

Drug diversion is the **illegal distribution or abuse/use of prescription drugs** away from the intended end user or a legitimate source.

Each Registrant must do what the law requires so that the drugs stay in the closed system of distribution and the drugs are not diverted onto the streets!

Drug Diversion:
It would never
happen here!

99% of the time Diversion happens
from the inside.

The #1 reason - People's life
circumstances change in an instant

Diversion Case Review



Office of Research Integrity and Compliance
Research Compliance and Regulatory Affairs



Drug Enforcement Administration

Orville O. Greene
Special Agent in Charge

Detroit
[@DEADetroitDiv](#)

April 28, 2023
Contact -

For Immediate Release

For Immediate Release

August 30, 2018

For Immediate Release

Contact: Brian McNeal

Phone Number: (571) 362-1498

Record settlement reached in University of Michigan hospital drug diversion civil penalty case

DETROIT - The Drug Enforcement Administration and United States Attorney's Office for the Eastern District of Michigan today announced that the University of Michigan Health System has agreed to pay the United States **\$4.3 million** as part of a settlement resolving allegations that UMHS violated certain provisions of the Controlled Substances Act, 21 U.S.C. §§ 801-904. The settlement, which is civil in nature, resulted from a years-long Drug Enforcement Administration investigation of UMHS's handling of controlled substances. It is the nation's largest settlement of its kind involving allegations of drug diversion at a hospital.

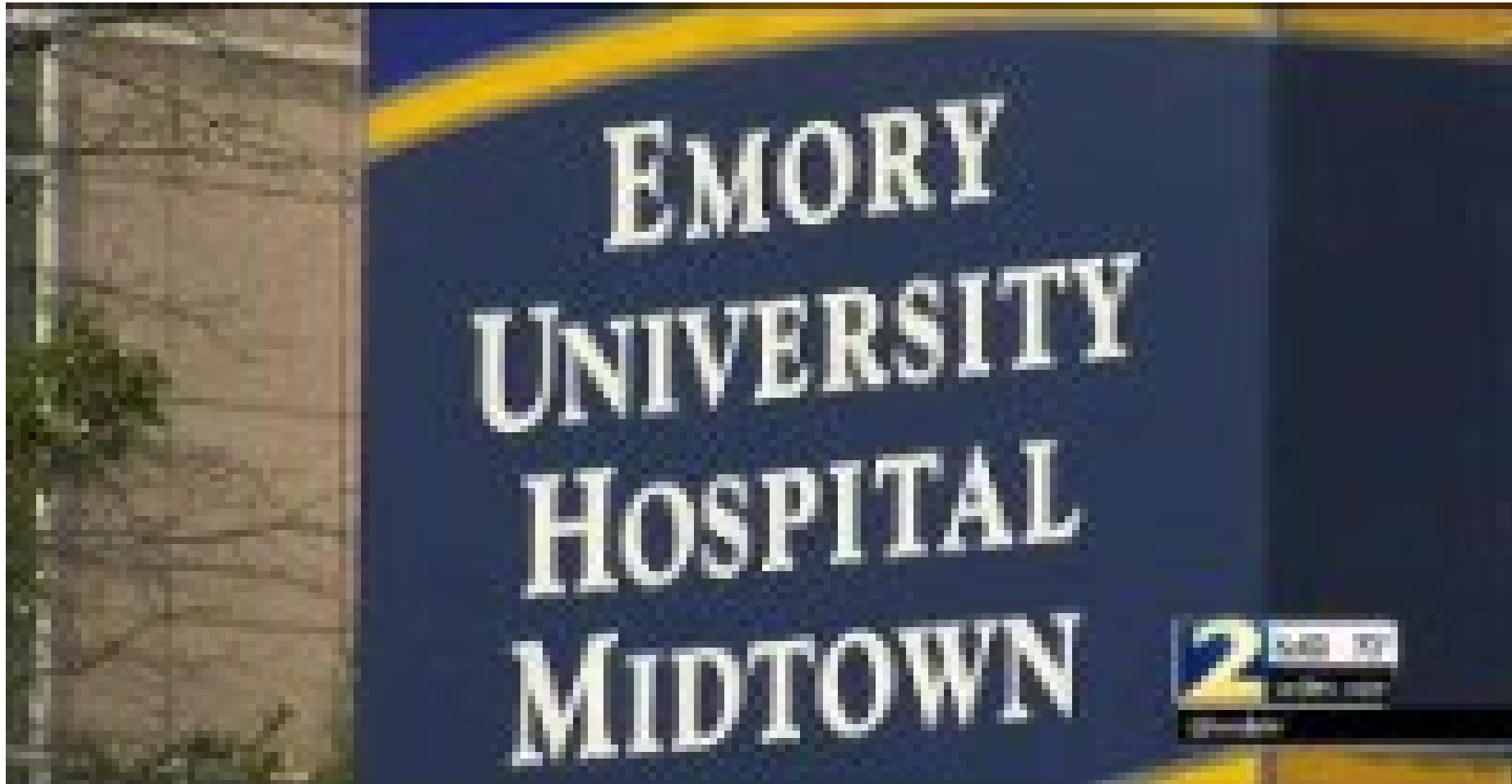
DEA began its investigation after two tragic incidents occurred in December 2013 involving two UMHS employees – a nurse and an anesthesiology resident. Both overdosed on opioids, including fentanyl, at a UMHS facility. The nurse's overdose was fatal.

dispensing
with saline solution be-



stances to respond to emergencies.
tampered with the
and replaced the drug with a clear
locked narcotics supply cabinet and

RALEIGH, N.C. – A former Fuquay-Varina nurse was sentenced today to 48 months



<https://emorywheel.com/drugs-scam-costs-university-health-system-millions/>

The Law: Regulatory Requirements

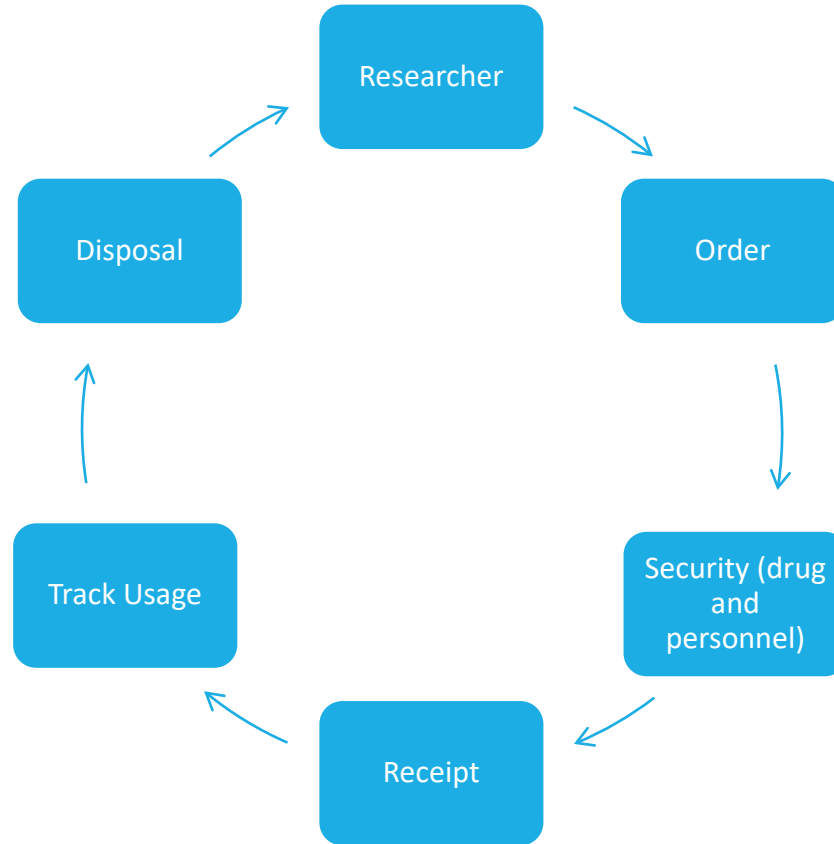
Federal Requirements (DEA
Registrants only)– 21 CFR Part 1300
to end

State Regulations (All Registrants) –
O.C.G.A Title 16, Chapter 13, Articles
1-3, O.C.G. A Rule 480-7-04

Each licensee is responsible for
knowing and complying with all the
regulations required by the license.

Researcher Responsibility:

Keeping drugs inside the closed system of distribution



100% Compliance

Due Diligence	Diversion Awareness	Standards	Policy
Proper Recordkeeping	Drug Accountability	Procedures	Reporting
Know the Laws & Penalties	Understand <u>ALL</u> the Regulations	Registration	Security Requirements

Future Training Topics:

- Obtaining Proper Licensing – Pre-Registration Assistance & Proper Security
- What do I do once I receive my license? Setting up my drug binders
- What's a controlled substance and what's a dangerous drug?
- How do I conduct an Inventory? (Initial, Biennial or Annual)
- Ordering and Receiving Drugs Properly
- Current Use Forms. Which forms do I use?
- Disposing of Drug Properly
- Maintaining Drug Accountability
- Theft/Loss Reporting? It is a BIG Deal!
- Who do these controlled substances belong to? Abandoned drugs
- Conducting Self Inspections
- What happens when I retire or leave Emory?

Register for Training Sessions here:

[Meeting Registration - Zoom](#)



MANAGING CONTROLLED SUBSTANCES & DANGEROUS DRUGS IN RESEARCH

Come learn how to manage your drugs and ask your pressing questions!

Presented by the Office of Research Integrity and Compliance (ORIC)
part of Research Compliance and Regulatory Affairs (RCRA)

Managing Controlled Substances & Dangerous Drugs in Research

Date & Time

You can choose to attend one or more of the following sessions.

- Nov 8, 2023 12:00 PM
- Dec 13, 2023 12:00 PM
- Jan 10, 2024 12:00 PM



Office of Research Integrity and Compliance
Research Compliance and Regulatory Affairs

Our contact info

Office email: oric@emory.edu

Office Website: <https://rcra.emory.edu/oric/index.html>

Maria Davila

Email: maria.davila@emory.edu

Phone: [404-712-8676](tel:404-712-8676)

Margaret Huber

Email: mhuber@emory.edu

Phone: [404-727-2233](tel:404-727-2233)

Danisha Biossat

Email: danisha.biossat@emory.edu

Phone: 404-251-1216



Office of Research Integrity and Compliance
Research Compliance and Regulatory Affairs



Thank you!
Any Questions?



EMORY
UNIVERSITY

Office of Research Integrity and Compliance
Research Compliance and Regulatory Affairs